I. Remarks

Claims 1-7 and 9-20 are currently pending. Claim 1, 11, and 12 stand withdrawn pursuant to a restriction requirement and a species election. Claim 8 has been canceled by this response without prejudice.

Claims 7, 9, and 10 have been amended with this response. Support for these amendments are found throughout the instant specification and particularly at paragraphs [0058] and [0228]. Therefore, these amendments do not add new matter. Applicants respectfully request their entry.

II. Claim objections

A) Claims 13 and 14 stand objected to by the Office based on their failure to comply with 37 C.F.R § 1.121. As noted by the Office, the amended claims submitted by Applicants in the response filed August 19, 2004 did not fully comply with the requirements of 37 C.F.R. § 1.121. These amended claims were not in compliance because claims 13 and 14 failed to show deleted matter. This was an inadvertent mistake, which Applicants have corrected by re-submission of the amended claims attached herein as Appendix A.

As discussed over the phone with Examiner Schnizer, Applicants have re-submitted these claims as Appendix in order to keep the prosecution record clear. They are identical in content to the claims submitted August 19, 2004; only changes to form were made to bring them into compliance with the requirements of 37 C.F.R. § 1.121. Therefore, they do not add new matter. Applicants regret any confusion or inconvenience that this may have caused.

B) Claims 2, 3, 7-10, and 13-20 stand objected to because they recite non-elected subject matter. Applicants note this objection but respectfully decline to make amendments until allowable subject matter has been identified.

C) Claim 7 stands objected to for a misspelling of "MCP-4" incorrectly as "MDP-4". Applicants have corrected this inadvertent error.

III. Claim rejections under 35 U.S.C. § 102(b)

Claims 7-10 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Hieshima et al. (J. Immunol. 159: 1140-1149, 1997). Specifically, the Office alleges that Hieshima teaches expression vectors encoding PARC fused to a SEAP (see page 10, third full paragraph, first line of the Office Action mailed February 24, 2004.) The Office concludes that, with these teachings, Hieshima anticipates all elements of the instant invention. Applicants respectfully traverse.

Applicants have amended claim 7 to claim the embodiment of the instant invention where the polynucleotide comprises a first polynucleotide encoding an immunostimulatory factor, a second polynucleotide that modulates the expression of the first polynucleotide, and a third polynucleotide encoding for a tumor-associated antigen. Hieshima does not anticipate the instant claims because Hieshima does not teach an expression vector encoding PARC fused to a polynucleotide encoding for a tumor-associated antigen. Therefore, Hieshima does not teach all elements of claim 7 and those dependent therefrom. Absent all elements, Hieshima cannot anticipate the invention as claimed. Applicants therefore respectfully request removal of this rejection.

IV. Claim rejections under 35 U.S.C. § 103(a)

Claims 2, 3, 7-10, and 13-20 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Glenn et al. (U.S. Patent No. 5,980,898 issued 11/9/99) in view of Staats et al. (U.S. Patent No. 6,270,758 issued 8/7/01.) In particular, the Office has concluded that it would have been obvious to one of ordinary skill at the time of the instant invention to utilize PARC as a chemokine adjuvant in the invention of Glenn based on Staats' disclosure that PARC is a chemokine adjuvant useful in Staats' methods.

Applicants respectfully traverse. The instant invention is not obvious in view of the references cited. The Office has failed to establish a prima facie case of obviousness because there is no suggestion or motivation to modify the Glenn reference with the teachings of the Staats reference. A statement that the modification of Glenn in light of Staats to meet the claimed invention is within the ordinary skill of the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references, even if the references provide the individual components of the claimed invention. Moreover, the fact that references can be combined does not render the combination obvious unless the prior art also suggests the desirability of the combination. Applicants respectfully assert that there is no motivation, nor has the Office provided a motivation, to modify the invention of Glenn with the teachings of Staats.

Glenn and Staats references each utilize a distinct immunization site- transcutaneous and mucosal, respectively. Applicants assert that the Office has not provided a teaching that adjuvants useful in a transcutaneous immunization are necessarily useful in mucosal administration. Rather, the Office has concluded that, because Glenn lists potential suitable chemokines for their methods, any chemokine cited in another reference is suitable for combination with Glenn. This ignores the fact that the chemokines cited in Glenn and those cited by Staats (particularly PARC) represent different chemokine classes, which do not necessarily share enough identity to simply be considered substitutions for one another[1]. Indeed, Hieshima et al. teaches that PARC, unlike "MIP-1α and most other CC chemokines, PARC is not chemotactic for monocytes" and also teaches that PARC's binding to lymphocytes is not inhibited by the chemokines MIP-1α or RANTES, among others[2]. These significant differences between PARC and other CC chemokines[3] with respect to monocyte and lymphocyte interaction provide strong evidence that PARC was not viewed, and cannot now be viewed, as a simple substitute to the chemokines listed by Glenn.

The skilled artisan would therefore not have been motivated to substitute PARC for those already provided by Glenn because there is no teaching or suggestion that, as a chemokine with significantly different properties, it would have been useful in Glenn's transcutaneous methods. Therefore, the skilled artisan would not have found the substitution of PARC in the methods of Glenn obvious based on Staats. Absent Applicants' teaching that PARC is useful to improve vaccination using dendritic cells, the skilled artisan would have likely been dissuaded from using PARC in Glenn's method due to its different properties taught by the prior art. Therefore, Applicants respectfully request that this rejection be withdrawn.

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[1] Chemokine adjuvants cited by Glenn are "defensins 1 or 2, RANTES, MIP1-α, MIP-2, interleukin 8" at column 9, lines 43-56 while chemokine adjuvants cited by Staats are "LARC, PARC, MDC, TARC, SLC, and FKN" at column 7, lines 29-42.

[2] See Hieshima et al. at page 1146, column 2 in the discussion.

[3] The chemokines with different behaviors include both MIP-1α and RANTES, which are cited as chemokine adjuvants useful in the Glenn reference.

V. Claim Amendments under 37 C.F.R. § 1.121

1. (Withdrawn) An isolated polynucleotide encoding a secreted immunostimulatory factor that is differentially expressed in an antigen presenting cell selected from the group consisting of TARC, monocyte chemoattractant protein-4 (MCP-4), MDC, ecalectin, MCP-2, eotaxin 3, or biologically active fragments thereof.

2. (Previously presented) The polynucleotide of claim 13 further comprising a first and second promoter, wherein the first and second polynucleotides are under the transcriptional control of the first and second promoters, respectively.

3. (Previously presented) The polynucleotide of claim 13 further comprising a single promoter, wherein the first and second polynucleotides are under the transcriptional control of the single promoter.

4. (Original) A gene delivery vehicle comprising a polynucleotide of claim 1.

5. (Original) A host cell that comprises a polynucleotide of claim 1.

6. (Original) An array of probes comprising a polynucleotide of claim 1 bound to a chip.

7. (Currently amended) An isolated polynucleotide comprising a first polynucleotide encoding a secreted immunostimulatory factor that is differentially expressed in an antigen presenting cell selected from the group consisting of PARC, TARC, monocyte chemoattractant protein-4 (M[[D]]CP-4), MDC, ecalectin, MCP-2, eotaxin 3, or biologically active fragments thereof and a second polynucleotide that modulates the expression of the first polynucleotide and a third polynucleotide encoding a tumor-associated antigen.

8. (Canceled) A polynucleotide of claim 7, further comprising a polynucleotide encoding an antigen.

9. (Currently amended) A gene delivery vehicle comprising the polynucleotides of claim 7 ~~or 8~~.

10. (Currently amended) A host cell comprising the polynucleotides of claim 7 ~~or 8~~.

11. (Withdrawn) A method for inducing an immune response in a subject comprising administering an effective amount of the polynucleotide of claim 1, to the subject.

12. (Withdrawn) A method of modulating the genotype of an antigen presenting cell, comprising introducing into the cell a polynucleotide of claim 1.

13. (Previously presented) An isolated polynucleotide encoding a secreted immunostimulatory factor that is differentially expressed in an antigen presenting cell selected from the group consisting of PARC, TARC, monocyte chemoattractant protein-4 (MCP-4), MDC, ecalectin, MCP-2, eotaxin 3, or biologically active fragments thereof and further comprising a second isolated polynucleotide encoding for a tumor-associated antigen.

14. (Previously presented) A composition comprising an isolated polynucleotide encoding a secreted immunostimulatory factor that is differentially expressed in an antigen presenting cell selected from the group consisting of PARC, TARC, monocyte chemoattractant protein-4 (MCP-4), MDC, ecalectin, MCP-2, eotaxin 3, or biologically active fragments thereof and a second, separate isolated polynucleotide encoding a tumor-associated antigen.

15. (Previously presented) The composition of claim 14, wherein the separate polynucleotides are each under the transcriptional control of a promoter.

16. (Previously presented) The polynucleotide of claim 7 further comprising a polynucleotide encoding for a tumor-associated antigen.

17. (Previously presented) A composition comprising the polynucleotide of claim 7 and a second, separate polynucleotide encoding a tumor-associated antigen.

18. (Previously presented) The composition of claim 17, wherein the separate polynucleotides are each under the transcriptional control of a promoter.

19. (Previously presented) A gene delivery vehicle comprising the composition of claim 13 or 14.

20. (Previously presented) A host cell that comprises the composition of claim 13 or 14.

VII. Conclusion

No fee is deemed necessary in connection with the filing of this communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

Respectfully submitted,

5/17/05
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